DOCKET NO.: IBIS0002-100 (IBIS-0368) **PATENT**

REMARKS

Claims 36-50 have been cancelled herein. New claims 51-68 have been added. Support for the new claims can be found at, for example, page 12, lines 1-11, page 13, lines 4-13, page 15, lines 2-9 and in originally filed claims 23-25. No new matter has been added.

As a preliminary matter, Applicants' undersigned representative thanks the Examiner for the interview conducted on November 13, 2003. Applicants' representative would like to thank the Examiner for the opportunity to discuss the status of the claims under examination and to discuss the references cited in the Office Action.

I. The Claimed Invention Is Novel and Not Obvious

Claims 17-25 have been rejected as allegedly being anticipated by or obvious in view of some or all of the following references: 1) U.S. Patent No. 6,393,367, 2) U.S. Patent No. 6,055,487, 3) U.S. Patent No. 6,018,713, 4) Muddiman et al., Anal. Chem., 1997, 69, 1543-1549, and 5) Muddiman et al., Anal. Chem., 1996, 68, 3705-3712. Although Applicants maintain that claims 17-25 recited novel and non-obvious subject matter, claims 17-25 have been cancelled without prejudice to their presentation in another application.

New claims 51-68 recite a service for providing characterizing information about a bioagent. A database of base composition signatures that are indexed to molecular masses of amplification products of known bioagents is provided. The database is interrogated with an identification query comprising a measured molecular mass of a bioagent. The measured molecular mass is of an amplification product comprising a variable region that is present within a gene involved in translation, replication, recombination, repair, transcription, nucleotide metabolism, amino acid metabolism, lipid metabolism, energy generation, uptake, or secretion. The variable region is flanked by a pair of highly conserved regions. A response providing characterizing information for the bioagent that is generated by the database is delivered. Particular representative genes include, for example, DNA polymerase III beta, elongation factor TU, heat shock protein goEL, RNA polymerase beta, phosphoglycerate kinase, DADH dehydrogenase, DNA ligase, DNA topoisomerase, elongation factor G, and RNAse P.

None of the references of record teach the service recited in claim 51, let alone any of the genes recited in claims 52-62 or additional elements recited in claims 63-68. Thus, claims 51-68 are novel in view of the references of record. Further, the combination of any of the references of record fails to produce a service recited in claim 51, let alone claims 52-68. Thus, claims 51-68 are not obvious in view of the references of record.

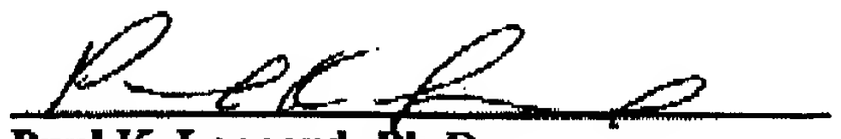
The Office Action asserts that both U.S. Patent No. 6,055,487 and U.S. Patent No. 6,018,713 report interactive ordering of testing at a central laboratory with computer network reporting of the test results. The Office Action further asserts that U.S. Patent No. 6,055,487 reports "microbiology testing" as one particular type of test result. Indeed, U.S. Patent No. 6,055,487 actually reports that additional uses of the remote laboratory can be in "the field of microbiology, as many microbiology tests have been reduced to simple devices which can be easily handled by robot. The remote laboratory can be configured to also include microbiology analysis." Thus, U.S. Patent No. 6,055,487 simply reports using the service reported therein to provide a response for microbiology laboratory tests obtained in a clinical environment. U.S. Patent No. 6,055,487 does not teach or suggest using the service reported therein as a means to identify bioagents. Identification of bioagents, particularly those present in samples from outside a clinical environment, is not taught in U.S. Patent No. 6,055,487. Additional features recited in the present claims, such as the type of gene and the particular gene, are neither taught nor suggested by the references of record.

There is no motivation to modify the computer-aided medical reporting systems of either U.S. Patent No. 6,055,487 or U.S. Patent No. 6,018,713 to produce Applicants' claimed service. Indeed, neither U.S. Patent No. 6,055,487 nor U.S. Patent No. 6,018,713 teach or even suggest mass spectroscopy analysis of samples containing bioagents in order to identify any bioagents therein. It is only upon consideration of Applicants' disclosure that such an idea comes to mind. The fact that references can be found that report mass spectroscopy analysis of DNA, or any other feature recited in the pending claims, is of no moment in considering motivation to modify a reported method. "A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." *In re Kotzab*, 217 F.3d 1365,

1369, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000). "The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time." *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (quoting *Interconnect Planning Corp. v. Feil*, 774 F. 2d 1132, 1138, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985). To establish a *prima facie* case of obviousness, "there must be some teaching, suggestion or motivation in the prior art to make the specific combination that was made by the applicant." *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998). "In other words, the examiner must show reasons that the skilled artisan, confronted with he same problem as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). Further, citing references which merely indicate that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would have been obvious. *Ex Parte Hiyamizu*, 10 U.S.P.Q.2d 1393 (Bd. Pat. App. Int. 1988).

Thus, in view of the foregoing, Applicants respectfully submit that new claims 51-68 are in condition for allowance.

Respectfully submitted,



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